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Oncology Clinical Trials and Insurance Coverage: An Update in a Tenuous Insurance Landscape

Running Title: Insurance and clinical trials

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Precis: The heterogeneous state and federal insurance laws for oncology clinical trial coverage are confusing for healthcare providers, patients and other stakeholders. There needs to be clearer explication and education about clinical trial coverage to help improve patient access.

Keywords: insurance, clinical trials, Affordable Care Act, oncology, Medicaid, Medicare

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Introduction

Clinical trials are a crucial component in the advancement of cancer treatment and cancer care. However, enrollment in clinical trials continue to lag due to multiple variables including insurance-based disparities in coverage.¹⁻⁶ At the level of the healthcare system, lack of provider knowledge and inconsistent support or initiation of a discussion about clinical trials impede accrual.^{7,8} The poor enrollment growth is worrisome as studies have shown increased survival among participants of oncologic clinical trials compared to their non-clinical trial counterparts.^{9,10} Furthermore, a study evaluating life years gained through participation in Southwest Oncology Group (SWOG) clinical trials revealed a 3.34 million life years gain and a \$125 return on investment per life year gained.¹¹ Nevertheless, despite the remarkable progress in cancer treatment secondary to clinical trials, insurance coverage has remained a barrier for enrollment.^{3,12}

As federal legislators seek to change key components of the ACA and state legislators fine-tune requirements for enrollment and participation in Medicaid, it is important to gain an understanding of the current insurance landscape for coverage of oncology clinical trials. To this end, the objective of this review is to present a current overview of federal and state laws, regulations and agreements on insurance coverage for oncology clinical trials. In addition, we seek to understand the initiation and extent of state laws for private insurers on clinical trial coverage to better understand how patient access to clinical trials maybe affected by repealing the current ACA statute requiring coverage.

Methods

To identify summaries of state and federal law(s) on oncology clinical trial coverage we used Westlaw to identify the current statues, regulations and agreements on clinical trial coverage for private insurers and Medicaid for each state and the District of Columbia. Westlaw was queried with the keywords--*clinical trials* and *insurance*. Subsequently, the statute number, date of enactment, effective dates and services covered were aggregated into a table.

Medicare and Oncology Clinical Trial Coverage

Since the enactment of Medicare and Medicaid in 1965, there have been numerous amendments that have expanded the scope and coverage of these government programs. For patients over the age of 65 enrollment in oncology clinical trials have been low compared to their younger counterparts^{13,14}. The age-based disparity in oncology clinical trial enrollment is significant as this population is disproportionately diagnosed with cancer.¹⁵ Reasons for poor

participation include a multifactorial interplay of physician, patient and trial related barriers.¹⁶ To help address this issue, in 2001 former President Clinton directed the federal Medicare program to issue a special National Coverage Determination (NCD) that authorized payments for the costs of routine care and research-related complications for clinical trials.¹⁷ The NCD has specific regulations regarding what is included in “routine costs” and only trials with therapeutic intent are included; thus, excluding most Phase I and many Phase II studies. Implementation of the NCD made noticeable progress in improving enrollment of Medicare aged patients to oncology trials. Specifically, Unger et al’s study evaluating enrollment of Medicare-aged patients in clinical trials showed a 13% increase in enrollment among the Medicare population to SWOG trials three years from the inception of the NCD.^{15,18} However, the NCD still left unaddressed, the coverage concerns of the roughly 86% of the population not covered by Medicare.¹⁹

Medicaid and Oncology Clinical Trial Coverage

Although the ACA addresses oncology clinical trial coverage by private insurers, it leaves coverage under Medicaid up to the states. Currently, only 10 states and the District of Columbia (DC) require Medicaid to cover the routine cost of clinical trials (Table 1). Conversely, 39 states exclude the coverage of clinical trials in their scope of services and/or pharmacy billing services for Medicaid. All the states with coverage of clinical trials through Medicaid have enactment and effective dates prior to the enactment of the ACA. In our search of their scope of services under Medicaid, Pennsylvania appeared unclear about the coverage of clinical trials. Interestingly, among the states requiring Medicaid coverage for clinical trials, Alaska, California, Indiana, Iowa, Maryland, Montana, Vermont, West Virginia, and DC participated in the Medicaid expansion under the ACA. On the other hand, despite having laws for clinical trial coverage through Medicaid, Texas and North Carolina elected to not implement the ACA Medicaid expansion.

The heterogeneity of Medicaid coverage for clinical trials across states warrants further evaluation as multiple studies have shown an association between lower socioeconomic status and late disease presentation.²⁰⁻²² Specifically, Medicaid patients with breast, cervical, colorectal and prostate cancer are more likely to present with a later disease stage than their privately insured counterparts.²³⁻²⁹ Due to their late disease presentation and worse survival, this population may benefit from increased access to clinical trials through Medicaid as they have been shown to improve survival.⁹⁻¹¹

The ACA and Oncology Clinical Trial Coverage

Prior to passage of The Patient Protection and Affordable Care Act (ACA), private insurers were reluctant to cover any cost associated with a clinical trial despite reports that the incremental cost increase for trial participation was 10% or less.³⁰⁻³² The ACA is the first federal law requiring private insurers to cover the routine cost of clinical trials under section 2709.³³ The law stipulates “*[the] clinical trial is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition.*”³⁴ As a result of the ACA, individuals with “*group health plan[s], a health insurance issuer in the group and individual health insurance market [plans]*” can elect to participate in clinical trials provided they meet the trial’s eligibility criteria.³⁵

Health plans covered by the Employee Retirement Income Security Act (ERISA) are also required to adhere to the ACA clinical trial coverage guidelines as these plans are bound by federal laws.³³ Under the law, insurers cannot deny coverage for diagnostic imaging, laboratory test or procedures considered standard of care because of patient participation in clinical trials. This is noteworthy as in 2010 only 18 states met the clinical trial coverage requirements currently outlined in the ACA.³⁶ Approved trials include phases I, II, III or IV clinical trials that are federally funded, FDA approved Investigational New Drugs (IND) or IND application exempt drugs.³⁷

Although the ACA law increases access to oncology clinical trials, grandfathered plans and Medicaid are not required to cover the cost of clinical trials.³⁸ The ACA describes grandfathered plans as plans with current coverage guidelines that precede the March 27, 2013 enactment of the ACA. In order to maintain their grandfathered status, these plans cannot make significant changes to coverage, benefits or cost sharing.^{36,39} This loophole in coverage is notable as studies have shown an association between insurance-based barriers and clinical trial enrollment.⁴⁰⁻⁴² In the 2016 Employer Health Benefits Survey by the Kaiser Foundation, 23% of firms reported at least one grandfathered plan. Furthermore, 23% of employees in the survey were enrolled in grandfathered plans.⁴³

Due to its recent implementation, the effects of the ACA on oncology clinical trial coverage and subsequent enrollment is still evolving. An examination of clinical trial coverage in Kansas among adults aged 19-64 projected a 3% increase in clinical trial coverage under the ACA.⁴⁴ In their institutional review of large early phase cancer clinical trials, Kehl et al noted improved insurance clearance rates among the privately insured post ACA.⁴⁵ However, a survey of 252 cancer research centers and community based institutions showed continued insurance

barriers to clinical trials with denials of coverage or delays. Grandfathered plans, out of network providers/sites and claims by insurers that they do not cover clinical trial, were the most common reasons for denial of coverage.⁴⁶ These findings indicate that there might be some misperception among insurers and healthcare providers about clinical trial coverage under the ACA. This issue is further compounded by confusion on the part of employers about the grandfathered status of their health plans.⁴³

State Statutes and Private Insurer Coverage for Oncology Clinical Trials

Only 33 states and the District of Columbia had enacted statutes or regulations requiring private insurance coverage for the routine cost of clinical trials prior to the ACA marketplace insurance going into effect on January 1st, 2014 (Table 2). Though they do not have statutes addressing coverage of clinical trials, Florida, Georgia, Michigan, Nebraska, New Jersey and South Carolina have agreements with private insurers for coverage of the routine cost of care associated with clinical trials. Currently based on our search of Westlaw 11 states have no laws or agreements with private insurers requiring clinical trial coverage.

There are considerable differences in the type and phase of private insurer clinical trial coverage by states (Table 3). Some states only cover specific phases of oncology clinical trials. For example, statutes in Illinois, Louisiana, Missouri, Nevada, West Virginia and Wyoming do not cover phase I clinical trials. Discrepancies in phases of clinical trial coverage by state is significant as it indicates differences in access to clinical trials based on state. The ACA law remedies this disparity because it requires private insurers to cover all phases of clinical trials. Moreover, the ACA is a federal law which consequently supersedes current state law. To this end, significant changes to the ACA resulting in a repeal of insurance coverage, as currently outlined, would exacerbate state level disparities in access to clinical trials among the privately insured. Specifically, patients in states with limited coverage of all phases of oncology clinical trials may experience a reduction in access to phase I or II clinical trials.

Future Directions

As significant progress is made in cancer care delivery, it is important to ensure that all patients have access to cutting edge treatments. Our review of Medicaid, Medicare, the ACA and state law for private insurance has shown that there are significant legislative gaps in coverage for oncology clinical trials. A repeal of the clinical trial coverage component of the ACA may reduce access to phase I and II clinical trials among privately insured individuals in some states. Furthermore, under the ACA, grandfathered plans and Medicaid are not

adequately required to cover oncology clinical trials resulting in a coverage gap for individuals who fall into those groups. To help alleviate some of the legislative discrepancies in coverage we propose the following recommendations (Figure 1): 1) remove the exclusion of the grandfather clause in the Affordable Care Act, 2) require Medicaid in all states to cover the routine cost of care associated with oncology clinical trials, 3) require all states to have legislation requiring private insurers to cover oncology clinical trials independent of the federal ACA law.

With the Tax Cuts and Jobs Act of 2017 eliminating the tax penalty for lack of insurance, we anticipate there will be continued changes in access to oncology clinical trials as individuals make decisions about their insurance status. Furthermore, a recent correspondence to *the New England Journal of Medicine* by Sommers et al reveal a 20% reduction in ACA coverage gains between 2013 and 2016 under the Trump administration.⁴⁷ With these continued changes to components of the ACA, patients, healthcare providers and healthcare stakeholders will need clearer education about insurance coverage for clinical trials.

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Table 1: States with Medicaid Coverage for Oncology Clinical Trials

Alaska	Alaska Stat. § 21.42.415	7/1/2010	7/1/2010
California	Cal. Ins. Code § 10145.4	8/9/2001	1/1/2002
District of Columbia	D.C. Code § 31-2993.02	6/5/2008	6/5/2008
Indiana	Ind. Code § 27-8-25-8	5/7/2009	6/30/2009
Iowa	Iowa Code § 514C.26	2/23/2010	7/1/2010
Maryland	MD Code, Ins. § 15-827	4/28/1998	1/1/1999
Montana	Mont. Code § 33-22-153	3/27/2013	3/27/2013
North Carolina	N.C. Gen. Stat. § 58-3-255	10/18/2001	3/1/2002
Texas	Tex. Ins. Code § 1379.052	6/19/2009	9/1/2009
Vermont	Vt. Stat. tit. 8, § 4088b	4/26/2001	4/26/2001
West Virginia	W. Va. Code § 33-25F-2	3/8/2003	6/8/2003

Table 2: Overview of Private Insurer Coverage of Oncology Clinical Trials by State

Alabama	No				
Alaska	Yes	Alaska Stat. § 21.42.415	statute	7/1/2010	9/29/2010
Arizona	Yes	Ariz. Rev. Stat. § 20-1402.01	statute	4/24/2000	7/18/2000
Arkansas	No				
California	Yes	Cal. Ins. Code § 10145.4	statute	8/9/2001	1/1/2003
Colorado	Yes	Colo. Rev. Stat. § 10-16-104	statute	5/2/2009	7/1/2009
Connecticut	Yes	Conn. Gen. Stat. § 38a-542a	statute	7/6/2001	1/1/2002
Delaware	Yes	Del. Code tit. 18, § 3351	statute	6/25/2002	7/1/2002
District of Columbia	Yes	D.C. Code § 31-2993.02	statute	6/5/2008	6/5/2008
Florida	Yes		agreement	7/1/2010	7/1/2010
Georgia	Yes		agreement	2002	2002
Hawaii	No				
Idaho	No				
Illinois	Yes	215 Ill. Comp. Stat. 5/364.01	statute	8/24/2004	1/1/2005
Indiana	Yes	Ind. Code § 27-8-25-8	statute	5/7/2009	7/1/2009
Iowa	Yes	Iowa Code § 514C.26	statute	2/23/2010	7/1/2010
Kansas	Yes	Kan. Admin. Regs. § 40-4-43	regulation	6/4/2010	6/4/2010
Kentucky	Yes	Ky. Rev. Stat. § 304.17A-136	statute	3/24/2010	7/15/2010
Louisiana	Yes	La. Stat. § 22:1044	statute	7/12/1999	7/12/1999
Maine	Yes	Me. Stat. tit. 24, § 4310	statute	1999	1999
Maryland	Yes	MD Code, Ins. § 15-827	statute	4/28/1998	1/1/1999

Massachusetts	Yes	Mass. Gen. Laws ch. 175 § 110L	statute	8/10/2002	11/8/2002
Michigan	Yes		agreement	6/6/2001	6/6/2001
Minnesota	Yes	Minn. Stat. § 62Q.526	statute	5/21/2013	1/1/2014
Mississippi	No				
Missouri	Yes	Mo. Rev. Stat. § 376.429	statute	7/2/2002	7/6/2006
Montana	Yes	Mont. Code § 33-22-153	statute	3/27/2013	3/27/2013
Nebraska	Yes		agreement	11/1/2009	11/1/2009
Nevada	Yes	Nev. Rev. Stat. § 689B.0306	statute	6/12/2003	1/1/2006
New Hampshire	Yes	N.H. Rev. Stat. § 415:18-1	statute	6/12/2000	1/1/2001
New Jersey	Yes		agreement	2/16/2000	2/16/2000
New Mexico	Yes	N.M. Stat. § 59A-22-43	statute	3/14/2001	3/14/2001
New York	No				
North Carolina	Yes	N.C. Gen. Stat. § 58-3-255	statute	10/18/2001	3/1/2002
North Dakota	No				
Ohio	Yes	Ohio Rev. Code § 3923.80	statute	5/6/2009	8/4/2008
Oklahoma	No				
Oregon	Yes	Or. Rev. Stat. § 743A.192	statute	6/16/2009	1/1/2010
Pennsylvania	No				
Rhode Island	Yes	R.I. Gen. Laws § 27-18-74	statute	6/18/2012	1/1/1995
South Carolina	Yes		agreement	7/1/2010	7/1/2010
South Dakota	No				
Tennessee	Yes	Tenn. Code § 56-7-2365	statute	5/26/2005	7/1/2005
Texas	Yes	Tex. Ins. Code § 1379.052	statute	6/19/2009	9/1/2009
Utah	No				
Vermont	Yes	Vt. Stat. tit. 8, § 4088b	statute	4/26/2001	4/26/2001
Virginia	Yes	Va. Code § 38.2-3418.8	statute	3/28/1999	7/1/2000
Washington	Yes	Wash. Admin. Code § 284-43-5420	regulation	10/8/2012	11/8/2012
West Virginia	Yes	W. Va. Code § 33-25F-2	statute	3/8/2003	6/8/2003
Wisconsin	Yes	Wis. Stat. § 632.87	statute	3/24/2006	11/1/2006
Wyoming	Yes	Wyo. Stat. § 26-20-301	statute	3/12/2008	7/1/2008

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Table 3: Details of Private Insurer Oncology Clinical Trial Coverage by State*

Alaska	no limit	yes
Arizona	I, II, III, IV	yes
California	I, II, III, IV	yes
Colorado	no limit	no
Connecticut	phase III, until limit removed 7-13-2011	yes, until limit removed 7-13-2011
DC	no limit	no
Delaware	no limit	no
Illinois	II, III, IV	yes
Indiana	no limit	no
Iowa	no limit	yes
Kansas	I, II, III, IV	yes
Kentucky	no limit	yes
Louisiana	II, III, IV	yes
Maine	no limit	no
Maryland	I, II, III, IV	no
Massachusetts	I, II, III, IV	yes
Minnesota	I, II, III, IV	no
Missouri	II, III, IV	yes
Montana	I, II, III, IV	yes
Nevada	II, III, IV	yes
New Hampshire	III, IV, case-by-case for I, II	no
New Mexico	II, III, IV, until limit removed 4-7-2009	yes
North Carolina	II, III, IV	no

Ohio	no limit	yes
Oregon	no limit	no
Rhode Island	I, II, III, IV	no
Tennessee	I, II, III, IV	yes
Texas	I, II, III, IV	no
Vermont	no limit	yes
Virginia	II, III, IV, case-by-case for I	yes
Washington	I, II, III, IV	no
West Virginia	II, III, IV	no
Wisconsin	no limit	yes
Wyoming	II, III, IV	yes

*Unfortunately, our review of the agreements for Florida, Georgia, Michigan, New Jersey, Nebraska, and South Carolina did not reveal any relevant information about the details of clinical trial coverage; as a result, they were omitted from Table 3.

† This column refers to states with statutes that only cover oncology clinical trials.

Figure 1: Recommendations to address disparities in insurance coverage for oncology clinical trials

1. Remove the exclusion of the grandfather clause in the Affordable Care Act.
2. Require Medicaid in all states to cover the routine cost of care associated with oncology clinical trials.
3. Require all states to have legislation requiring private insurers to cover oncology clinical trials independent of the federal ACA law.